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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,694	08/13/2001	Jan C. Simon	24741-1525	1918

26633 7590 05/20/2005

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EXAMINER

DAVIS, RUTH A

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 05/20/2005

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/856,694
Filing Date: August 13, 2001
Appellant(s): SIMON ET AL.

Patricia Granados
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed on March 2, 2005.

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(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

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(7) *Grouping of Claims*

Appellant's brief includes a statement that claims 36 – 45 and 56 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

Bloomfield et al., "Hypericum and Depression", Copyright 1996, Prelude Press, Editor Jean Sedillos (Hypericum Homepage, or HHP)

The Merck Manual, Copyright 1995 - 2002,

www.merck.com/pubs/mmanual/section10/chapter111/111a.htm

5,151,534	Shroot et al.	9-1992
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4,021,553	Lacefield et al.	5-1977
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Valavicius et al., "Antitumor Activity of Herbs of the Lithuanian SSR", Trudy Akademii Nauk

Litovskoi, SSR, Series B, 1986, pp.110-113, translation by Ralph McElroy Translation

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Chavez et al., "Saint John's Wort", Hospital Pharmacy, Vol.32, Number 12, pp.1621-1632

Decosterd et al., "New Hyperforin Derivatives from Hypericum revolutum VAHL with Growth Inhibitory Activity against a Human Colon Carcinoma Cell Line", Helvetica Chimica Acta, Vol.72(1989)

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(10) *Grounds of Rejection*

The following grounds of rejection are applicable to the appealed claims:

Claims 36 – 45 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hypericum Homepage (Hypericum & Depression, Bloomfield et al., copyright 1996, Prelude Press, Editor J. Sedillos – copy made available from hypericum.com) in view of The Merck Manual (1995-2002), Shroot et al. (US 5151534) and Lacefield et al. (US 4021553).

Applicant claims a method for treating a condition selected from inflammatory skin diseases, precancerous conditions, geriatric skin or microbial skin infections comprising topical administration of an effective amount of a composition consisting of (a) pharmaceutically acceptable carrier and (b) an active agent consisting of (i) hyperforin or (ii) hyperforin and hypericin, to a subject in need thereof. Specifically, the condition is eczema, or is selected from exsiccation eczemas, hyperkeratotic hand/foot eczemas, contact eczemas, atopic dermatitis, neurodermatitis, lichen simplex, prurigo simplex, lymphoma, leukemia, epithelial precancerous conditions, tumor metastases or epithelial tumors. The subject is a mammal and the composition is a topical ointment with an effective amount of at least 15 micrograms hyperforin per ml, 0.02 – 20 mg/ml, 1 – 20 mg/ml or 10 mg/ml; or 15 micrograms/ml or 20 – 150 micrograms/ml hypericin.

The Hypericum Home Page (HHP) teaches that extracts of *Hypericum perforatum* (St. John's Wort) include hypericin and hyperforin, wherein the extracts exhibit anti-inflammatory and antibacterial effects when applied externally, or topically (p.3). HHP specifically teaches these anti-inflammatory and antibacterial effects are attributed to the hyperforin content (p.3).

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HHP does not teach a method for treating the claimed conditions with the claimed effective amounts of hyperforin/hypericin or to treat the specific conditions. However, since hyperforin was a known and commercially available product at the time of the claimed invention (see specification, page 12), it would have been obvious to one of ordinary skill in the art to use hyperforin and/or hyperforin and hypericin in a method for treating inflammatory skin conditions because of its disclosed anti-inflammatory effect. It would have been further obvious to one of ordinary skill in the art to purify hyperforin from St. John's Wort or extracts thereof, since HHP specifically identifies hyperforin as the active agent against inflammation when topically applied. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to purify hyperforin from St. John's Wort, or obtain existing hyperforin and apply it topically with a reasonable expectation for successfully treating inflammatory conditions.

In addition, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize effective volumes and concentrations as a matter of routine experimentation, since the active ingredient was a recognized result effective variable. Moreover, where the general conditions of a claim are disclosed in the prior art (in the instant case, hyperforin was known to exhibit anti-inflammatory effects when topically applied), it is not inventive to discover the optimum or workable ranges by routine experimentation (MPEP 2144.05 II A). Although the reference does not teach the hyperforin applied with a pharmaceutically acceptable carrier, it would have been further obvious to one of ordinary skill in the art to include a pharmaceutical carrier because it was standard practice to do so, at the time the claimed invention was made. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to use hyperforin in a method for treating external

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anti-inflammatory conditions with a reasonable expectation of success because of its known anti-inflammatory activity as disclosed by HHP.

HHP does not specifically teach the extracts are effective against eczema, or the other claimed conditions. However, at the time of the claimed invention, it was well known in the art that eczemas are characterized by inflammation (see "The Merck Manual"). Specifically, eczema, contact eczema, atopic eczema, hand and foot eczemas, and lichen simplex are each characterized as superficial inflammations of the skin of varying degrees. In further support, Shroot et al. teaches inflammatory diseases include dermatitis and eczema (col.1 line 12-15) and Lacefield teaches inflammatory conditions include atopic dermatitis, contact dermatitis, eczema, lichen simplex and chronic dermatoses. At the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to topically treat any of the aforementioned eczemas with hyperforin because of the anti-inflammatory activity as disclosed by HHP. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by HHP and Merck to topically apply hyperforin in a method for treating inflammation and eczemas with a reasonable expectation for success.

Claims 36, 38 – 45 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valavicius in view of Chavez et al.

Applicant claims a method for treating a condition selected from inflammatory skin diseases, precancerous conditions, geriatric skin or microbial skin infections comprising topical administration of an effective amount of a composition consisting of (a) pharmaceutically acceptable carrier and (b) an active agent consisting of (i) hyperforin or (ii) hyperforin and

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hypericin, to a subject in need thereof. The condition is selected from exsiccation eczema, hyperkeratotic hand and foot eczema, contact eczema, atopic dermatitis, neurodermatitis, lichen simplex, prurigo simplex, lymphoma, leukemia, epithelial precancerous conditions, tumor metastases or epithelial tumor. The subject is a mammal. The effective amount comprises at least 50 micrograms hyperforin/ml in an injectable form, 100 micrograms/microliter suitable for epicutaneous application, 50 micrograms/ml for systemic administration. The hyperforin is at least 90% pure.

Valavicius teaches that St. John's Wort extracts, specifically oil extracts, inhibits growth of sarcoma cells (abstract) and tumors in various organs in rats (mammals) (p.1-3 translation). Specifically, Valavicius teaches that intraperitoneal administration of the extracts at 0.25, 0.50, 1.0 and 2.0 mg/kg inhibits tumor growth in animals, or subjects in need thereof (p.2-3 translation). At the time the claimed invention was made, it was known in the art that oil preparations of St. John's Wort contain high concentrations of hyperforin (See Chavez, p.1622) and that intraperitoneal administration typically contains pharmaceutically acceptable carriers.

Valavicius does not teach the method wherein the claimed volumes and concentrations of hyperforin/hypericin are administered, the claimed modes of administration, or wherein the hyperforin is at least 90% pure. However, at the time of the claimed invention, St. John's Wort oil was known to have high concentrations of hyperforin. Since Valavicius teaches St. John's Wort oil is effective to inhibit tumor growth and St. John's Wort oil was known to have high concentrations of hyperforin, it would have been obvious to one of ordinary skill in the art to use the active agent of St. John's Wort oil (hyperforin) in a method for treating tumors with a reasonable expectation for successfully inhibiting tumor growth.

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At the time of the claimed invention, hyperforin was a known and commercially available product at the time of the claimed invention (see specification, page 12). Thus it would have been obvious to one of ordinary skill in the art to purify hyperforin from St. John's Wort or extracts thereof, since Valavivius uses St. John's Wort oil to inhibit tumor growth and because St. John's Wort oil was well known to contain high amounts of hyperforin. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to purify hyperforin from St. John's Wort, or obtain existing hyperforin and administer the active hyperforin with a reasonable expectation for successfully inhibiting tumor growth.

In addition, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize effective volumes and concentrations as a matter of routine experimentation, since the active ingredient was a recognized result effective variable. Moreover, where the general conditions of a claim are disclosed in the prior art (in the instant case, St. John's Wort containing hyperforin was known to exhibit anti-tumor growth effects when administered), it is not inventive to discover the optimum or workable ranges by routine experimentation (MPEP 2144.05 II A). Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to use hyperforin in a method for treating tumors with a reasonable expectation of success because of its known tumor inhibiting activity as Valavivius.

Claims 36, 38 – 45 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valavicis, Chavez, HHP and DeCosterd.

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Applicant claims a method for treating a condition selected from inflammatory skin diseases, precancerous conditions, geriatric skin or microbial skin infections comprising topical administration of an effective amount of a composition consisting of (a) pharmaceutically acceptable carrier and (b) an active agent consisting of (i) hyperforin or (ii) hyperforin and hypericin, to a subject in need thereof. Specifically, the condition is selected from eczema, exsiccation eczema, hyperkeratotic hand and foot eczema, contact eczema, atopic dermatitis, neurodermatitis, lichen simplex, prurigo simplex, lymphoma, leukemia, epithelial precancerous conditions, tumor metastases or epithelial tumor. The subject is a mammal, and the composition is a topical ointment and the effective amount is at least 15 micrograms hyperforin per ml, 0.02 – 20 mg/ml, 1 – 20 mg/ml, 10 mg/ml, at least 15 micrograms hypericin/ml or 20 – 150 micrograms hypericin/ml. The hyperforin is at least 90% pure.

Valavicius teaches that St. John's Wort extracts, specifically oil extracts, inhibits growth of sarcoma cells (abstract) and tumors in various organs in rats (mammals) (p.1-3 translation). Specifically, Valavicius teaches that intraperitoneal administration of the extracts at 0.25, 0.50, 1.0 and 2.0 mg/kg inhibits tumor growth in animals, or subjects in need thereof (p.2-3 translation). At the time the claimed invention was made, it was known in the art that oil preparations of St. John's Wort contain high concentrations of hyperforin (See Chavez, p.1622) and that intraperitoneal administration typically contains pharmaceutically acceptable carriers.

Valavicius does not teach the method wherein the claimed volumes and concentrations were used, modes of administration, or wherein the hyperforin is at least 90% pure. However, at the time of the claimed invention, St. John's Wort oil was known to have high concentrations of hyperforin. Since Valavicius teaches St. John's Wort oil is effective to inhibit tumor growth and

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St. John's Wort oil was known to have high concentrations of hyperforin, it would have been obvious to one of ordinary skill in the art to use the active agent of St. John's Wort oil (hyperforin) in a method for treating tumors with a reasonable expectation for successfully inhibiting tumor growth.

At the time of the claimed invention, hyperforin was a known and commercially available product at the time of the claimed invention (see specification, page 12). Thus it would have been obvious to one of ordinary skill in the art to purify hyperforin from St. John's Wort or extracts thereof, since Valavivius uses St. John's Wort oil to inhibit tumor growth and because St. John's Wort oil was well known to contain high amounts of hyperforin. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to purify hyperforin from St. John's Wort, or obtain existing hyperforin and administer the active hyperforin with a reasonable expectation for successfully inhibiting tumor growth.

In addition, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize effective volumes and concentrations as a matter of routine experimentation, since the active ingredient was a recognized result effective variable. Moreover, where the general conditions of a claim are disclosed in the prior art (in the instant case, St. John's Wort containing hyperforin was known to exhibit anti-tumor growth effects when administered), it is not inventive to discover the optimum or workable ranges by routine experimentation (MPEP 2144.05 II A). Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to use hyperforin in a method for treating tumors with a reasonable expectation of success because of its known tumor inhibiting activity as disclosed by Valavivius.

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Valavicius does not teach the method wherein the tumors are lymphoma, leukemia, or epithelial tumors. However, HHP teaches that extracts of *Hypericum perforatum* (St. John's Wort) have hypericin and hyperforin as active agents, wherein the extracts demonstrate anticancer properties and have been proven to inhibit tumor cells of the brain, lung and skin (p.4). In addition, DeCosterd teaches that extracts of *Hypericum* inhibit growth of colon carcinomas (abstract). Specifically, DeCosterd teaches derivatives of hyperforin exhibit the growth-inhibiting activity (abstract). At the time of the claimed invention, hypericin, hyperforin, derivatives thereof and extracts of *Hypericum* were well known as effective agents against cancers (or tumors) of various kinds, as evidenced by the cited references. Although HHP and DeCosterd do not specifically teach methods for treating cancers or tumors, the references certainly teach that St. John's Wort extracts, hypericin and hyperforin exhibit anti tumor activity. Since hyperforin was a known and commercially available product at the time of the claimed invention (see specification, page 12), it would have been obvious to one of ordinary skill in the art to use hyperforin and/or hyperforin and hypericin in a method for treating tumors because of its disclosed inhibitory effect on tumor growth (as evidenced by the cited references). Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to treat cancers (i.e. lymphoma, leukemia, epithelial tumors) with hypericin and hyperforin because of the demonstrated effectiveness in doing so in a variety of cancers.

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(11) *Response to Argument*

Claims 36 – 45 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hypericum Homepage in view of The Merck Manual, Shroot and Lacefield.

Appellant argues that the rejections are improper because St. John's Wort extracts are not equivalent to hyperforin or a combination of hyperforin and hypericin; that HHP teaches St. John's Wort extract contains over 10 compounds which treats depression; and that St. John's Wort extract is a complicated extract as evidenced by the cited references. Appellant additionally argues that HHP does not teach a purified application of hyperforin or hyperforin and hypericin for treating skin conditions, but that HHP is unclear as to what type of inflammation is being treated. Appellant finally argues that the statement to optimize amounts and carriers is in error; that Merck fails to cure the deficiencies of HHP; one could not assume that treatment of one inflammatory condition would work for all conditions; there is not reasonable expectation for success and that the references do not teach treating leukemia or lymphoma.

However, these arguments fail to persuade because the cited reference specifically identifies hyperforin as the active ingredient which exhibits the anti-inflammatory effect when topically applied. Since the reference specifically identifies the active agent, and the active agent was already isolated and known in the art (spec. p.12), it is maintained that one of ordinary skill in the art would have been motivated to topically treat anti-inflammatory conditions with hyperforin or hyperforin/hypericin, with a reasonable expectation for success. In addition, while the reference does teach St. John's Wort extracts contain many compounds, it is noted that the

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reference specifically identifies hyperforin as the active agent to exhibit the anti-inflammatory activity, as admitted by appellant (Appeal Brief, p.6-7).

Regarding appellant's assertion that HHP does not teach a purified application of hyperforin/hyperforin and hypericin for treating skin conditions, the reference does specifically teach that when St. John's Wort is applied topically, hyperforin is attributed with the anti-inflammatory activity. As indicated in the above rejection, isolated hyperforin was a known and commercially available product at the time of the claimed invention (see specification, page 12). In addition, it would have been obvious to one of ordinary skill in the art to purify hyperforin from St. John's Wort, since hyperforin is clearly disclosed as the effective agent in St. John's Wort to demonstrate anti-inflammatory activity when topically applied. Thus it would have been obvious to one of ordinary skill in the art to use hyperforin and/or hyperforin and hypericin in a method for treating inflammatory skin conditions because of its disclosed anti-inflammatory effect. As to appellant's argument that the reference does not teach hyperforin and hypericin, it is noted that the rejected claims do not require that both hyperforin and hypericin be present in the composition, thus the argument is not commensurate in scope with the claims.

Regarding appellant's arguments that it is not obvious to optimize amounts of active agents or to include carriers, it is reiterated that active agents are variables which achieve a recognized result and are therefore considered result effective variables. HHP specifically identifies hyperforin as the active agent in treating anti-inflammatory conditions, when topically applied. Therefore, at the time of the claimed invention, one of ordinary skill in the art would certainly have been motivated to use hyperforin in a method for treating inflammatory conditions, as well as optimize the most effective amount of active ingredient, with a reasonable

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expectation of success because of its known anti-inflammatory activity as disclosed by HHP. As to including a carrier, at the time of the claimed invention, it was standard practice in the art to administer active agents in combination with a carrier. HHP specifically identifies pharmaceutical forms include tablets, caplets, capsules, drops, tea and oils (p.2, or 99), each of which include pharmaceutically acceptable carriers.

Finally, regarding appellant's argument that treating one inflammation condition does not indicate that all conditions can be treated, the claims do not require each of the claimed conditions be treated, but that at least one of the conditions be treated. Since the claims do not require treatment of each of the presently claimed conditions (to include leukemia and/or lymphoma) the argument is not commensurate in scope with the claims. HHP specifically teaches hyperforin has anti-inflammatory activity when topically applied. Many of the claimed conditions are characterized by topical inflammation, as evidenced by the cited references, thus one of ordinary skill in the art would certainly have been motivated to treat such conditions with hyperforin with a reasonable expectation for success.

Claims 36, 38 – 45 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valavicius and Chavez.

Appellant argues that Valavicius is incorrectly interpreted in that the claims do not require treating cancer; and that the abstract is unclear whether the St. John's Wort and chamomile are administered and tested together or separately. Appellant argues that it is unclear what is in the oil extracts of Valavicius since there is no teaching of how the extracts are prepared, thus one could not determine what compound is exhibiting the anti-tumor activity. In

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addition, appellant argues that Chavez teaches the oil extracts are hypericin free and high in hyperforin, but does not say what the high amounts are. Appellant argues that Valavicius does not teach 90% purified hyperforin, but that Examiner is using improper hindsight; and that the reference does not teach hyperforin alone or hyperforin and hypericin alone with a carrier. Appellant further argues that Valavicius teaches away from the claimed invention because appellants have data suggesting that Valavicius are incorrect in their findings. Finally appellant argues that oil are not an effective carriers thus is not considered “pharmaceutically acceptable”; that oils are ingredients, not carriers; that the specification identifies the effective carriers to include creams, ointments and ethanol; and that the creams and ointments are superior to oil carriers thus work unexpectedly better than oils.

However, these arguments fail to persuade because claim 36 specifically identifies a precancerous conditions and claim 38 identifies epithelial tumors, tumor metastases, lymphomas and leukemia, each of which are types of cancer. In addition, Valavicius specifically identifies testing St. John’s Wort extracts alone in various cancers (see Table 1, p.3 of translation), wherein tumor growth was inhibited.

Regarding appellant’s argument that it is unclear what active agents exhibit the anti-tumor effect, it is reiterated that at the time the claimed invention was made, it was known in the art that oil preparations of St. John’s Wort contain high concentrations of hyperforin (See Chavez, p.1622). Thus one of ordinary skill in the art would have been motivated to use hyperforin as the active ingredient in the methods of Valavicius.

Regarding appellant’s argument that the reference does not teach a 90% purified hyperforin, it is noted that such compositions were well known and commercially available in

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the art at the time the claimed invention was made (see specification p.12). In addition, it would have been obvious to one of ordinary skill in the art to purify hyperforin from St. John's Wort oil, since hyperforin was known to exist in high concentrations, and since the oil is clearly disclosed to be effective against various tumor cell growth. In light of these known facts, one of ordinary skill in the art would have been motivated to use hyperforin purified from St. John's Wort oil in the methods of Valavicius with a reasonable expectation of successfully treating various tumors. As to appellant's argument that the reference does not teach hyperforin and hypericin, it is noted that the rejected claims do not require that both hyperforin and hypericin be present in the composition, thus the argument is not commensurate in scope with the claims. Regarding the use of a carrier, Valavicius administers the extracts intraperitoneally, which is standard practice to contain pharmaceutically acceptable carriers.

Regarding appellant's assertion that Valavicius is wrong in its findings since appellant has data contrary to the reference, appellant has failed to provide evidence to that effect. Appellants have not provided any evidence which supports the assertion that the methods of Valavicius do not work.

Finally, regarding appellant's arguments that oils are not pharmaceutically acceptable carriers, it is noted that the specification fails to define a pharmaceutically acceptable carrier. Since appellant does not in any way limit the term to include or exclude known and acceptable carriers, the phrase "pharmaceutically acceptable carrier" is properly interpreted to include oils. (see HHP, p.2 or 99 for further support). While the specification does identify carriers that work better than others, the claims merely require any pharmaceutically acceptable carrier, which includes oils. As to appellant's argument that creams, ointments and ethanol work unexpectedly

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better, the claims are not limited to these specific carriers, thus the argument is not commensurate in scope with the claims.

Claims 36, 38 – 45 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valavicius, Chavez, HHP and DeCosterd.

Appellant argues that the claims do not require treating cancer and that DeCosterd does not cure the deficiencies of HHP or Valavicius, but teaches derivatives of hyperforin, not hyperforin as active ingredients against cancers and/or tumors.

However, these arguments fail to persuade because as stated above, claim 36 specifically identifies a precancerous conditions and claim 38 identifies epithelial tumors, tumor metastases, lymphomas and leukemia, each of which are types of cancer. In addition, claim 38 also includes conditions such as lymphoma, leukemia, precancerous conditions, tumor metastases and epithelial tumors, which are considered cancers. Since the cited references each identify the active agents of St. John's Wort (to include hyperforin, hypericin, and derivatives thereof) are effective to inhibit various tumor (or cancer) growth, it would have been obvious to one of ordinary skill in the art to use hyperforin, hyperforin and hypericin, or derivatives thereof, in a method for treating tumors because of its disclosed inhibitory effect on tumor growth (as evidenced by the cited references). Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to treat cancers (i.e. lymphoma, leukemia, epithelial tumors) with hypericin and hyperforin because of the demonstrated effectiveness in doing so in a variety of cancers.

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

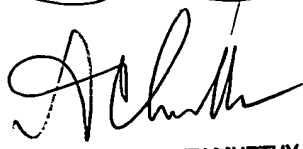
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